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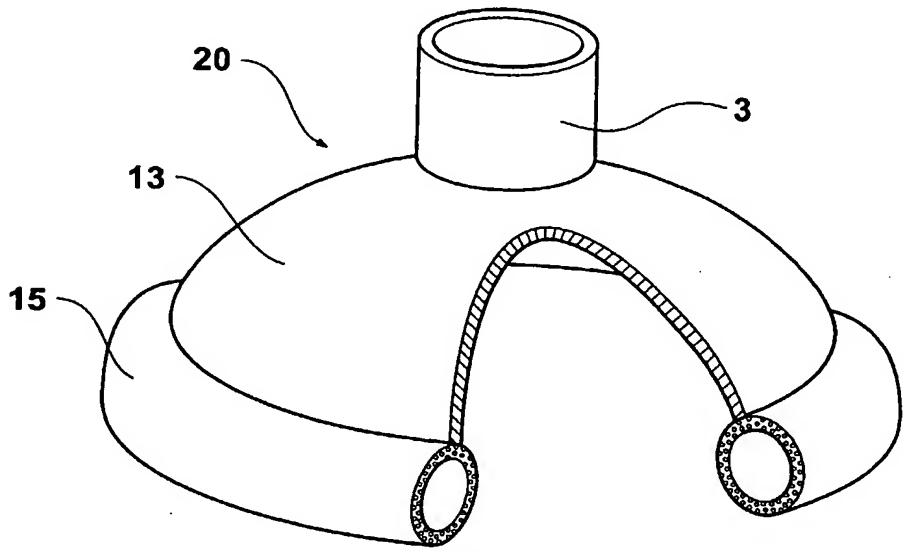
(54) Title: ANATOMICAL MASK



(57) Abstract: An anatomical mask is manufactured by moulding together a relatively hard shell material (13, 170) and a peripheral cushion (15, 210) of a thermoplastic elastomer. In one embodiment a foaming agent is present in the thermoplastic elastomer and expands the cushion (15) when the mould is opened. In another embodiment two moulds have a common upper part (120) by which the moulded shell (170) is transferred between the moulds. The lower part (140) may have a groove whereby a head band (300) is formed simultaneously with the cushion (210).

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ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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"ANATOMICAL MASK"

This invention relates to an improved anatomical mask and method of manufacturing the same. Examples of such masks are face masks designed to cover the nose and/or mouth which are used to supply e.g. a pilot, a diver, a firefighter or a hospital patient with a breathing gas mixture. A shell, usually transparent, incorporates at least one tubular orifice to which a gas supply line can be connected. Another type of anatomical mask is used to cover a tracheostomy, an opening in the neck into the trachea, so that a patient can be ventilated otherwise than through the nose and mouth. Other examples of anatomical masks are swimming goggles, industrial dust masks and breathing apparatus, having a shell fitted either with a window or a filter. All of these masks have in common a central, domed component, which may be a relatively hard shell, around the periphery of which is a relatively soft cushion to form an air seal against a particular area of a human or animal body. For most applications, particularly in the medical field, it is desirable that this shell is transparent. This however limits the choice of materials.

In one known way of making such masks the central component or shell is made separately from the annular cushion, typically by injection moulding of a transparent plastics material. The cushion, which is to deform to follow the contours of the body, is made typically in a separate injection or blow moulding operation or by rotational casting. It may be a gas injected and/or chemically foamed polymer, which of course need not be transparent. Alternatively it may simply be a ring of rubber or other elastomeric polymer. After the two components have been made they must be bonded together. This is usually done by hand.

This three-stage manufacturing procedure is time consuming and labour intensive, which affects the cost of the finished article.

A simpler and cheaper technique is to mould a clear plasticised PVC to have a thinned edge serving as the "cushion". This can be made in a single stage moulding operation and has the required optical characteristics, but it has the drawbacks that if the PVC is soft enough to provide the cushioned edge it is not rigid enough to form connections e.g. with airlines without separate connectors. In general the use of PVC is to be avoided due to the generation of hydrogen and chlorine when processed in manufacture or when incinerated during disposal.

A principal object of the present invention is to permit the avoidance of PVC yet provide a shell adequately clear and adequately rigid in a two-stage manufacturing process which requires no manual input.

In accordance with one aspect of the present invention there is provided a method of manufacturing an anatomical mask (as herein defined) which comprises forming or placing in a mould a central component of the mask comprising a first, relatively hard polymeric material and introducing into a mould a second relatively soft polymeric material to contact and bond to the periphery of the central component whereby the second polymeric material will form a cushion around the periphery of the central component.

Preferably the first polymeric material is transparent polypropylene and the second polymeric material is a thermoplastic elastomer.

The first polymeric material may be allowed at least partially to solidify before exposure to the second polymeric material.

In a first embodiment of the present invention said second relatively soft polymeric material may contain a foaming agent and the method comprises opening the mould after the second polymeric material has formed a skin where it contacts the mould but before the second polymeric material has fully solidified whereby the second polymeric material will expand to form a cushion around the periphery of the central component.

A removable barrier may be placed within the mould to define the periphery of a central area of the mould cavity, the first polymeric material being injected into said central area in a liquid state and allowed to solidify before removal of the barrier and injection into an outer area of the the mould cavity of the second polymeric material in a liquid state.

A gas from a source other than the foaming agent may be introduced into the cushion material before the latter has solidified.

A gas may be introduced under pressure into the second polymeric material before its introduction into the mould.

In accordance with a second embodiment of the present invention the central component may be moulded in a first mould and may then be transferred to a second mould the cavity of which has a peripheral enlargement in which the cushion is moulded in contact with the periphery of the first component.

In the said second embodiment each of the moulds may be of two parts, one part being common, said one part being transferred with the moulded first component to a second part of the second mould, the second part of the second mould differing from the second part of the first mould by said peripheral enlargement of the cavity.

The cavity of the first mould may be shaped to provide the first component with a thinned periphery which in the second mould is mated with a thinned periphery of the cushion.

The second mould may be formed with at least one groove communicating with said cavity to provide fastening means for the mask. Said groove may be formed in the surface of the second part of the second mould which confronts the first mould part when the mould is closed.

In accordance with another aspect of the present invention there is provided apparatus when used to carry out the first embodiment of the invention, the apparatus comprising a mould having two parts separable across a cavity defined between the parts when the mould is closed, the cavity having a central, relatively thin area to form the central component of the mask and an outer relatively thicker area into which the second polymeric material will be injected, said two areas being separable by a removable barrier which, when present in the mould, defines the periphery of the central component of the mask.

The barrier may be tubular and may be movable into or out of the mould through a tubular slot in one of the mould parts.

In accordance with yet another aspect of the present invention there is provided apparatus when used to carry out the second embodiment of the invention, the apparatus comprising two moulds each having two parts separable across a cavity defined between the parts when the mould is closed, the cavity of the second mould having a peripheral enlargement in which the cushion will

be moulded, one part of the two moulds being common and the other part of the second mould differing from the other part of the first mould by the peripheral enlargement of its cavity in which the cushion will be moulded.

Said other part of the first mould may have a step at the periphery of the cavity which will provide the first component with a thinned periphery.

Said other part of the second mould may be provided with a groove communicating with said peripheral enlargement to provide fastening means for the mask.. The groove may communicate at both ends with said peripheral enlargement to provide the mask with an elastomeric head band.

Preferred embodiments of the present invention will now be described by way of non-limitative example with reference to the accompanying drawings, in which:

Figure 1 illustrates an anaesthetic mask made in accordance with a first embodiment of the present invention partially cut away to show internal detail;

Figures 2-5 are similar sectional elevational views through a mould by which the mask of Figure 1 is made, illustrating successive stages of the manufacturing process;

Figure 6 illustrates an anaesthetic mask made in accordance with a second embodiment of the present invention partially cut away to show internal detail;

Figures 7-11 are similar sectional elevational views through a mould by which the mask of Figure 6 is made, illustrating successive stages of the manufacturing process, and

Figure 12 illustrates a modification of the mask of Figure 6.

The mould 10 of Figures 2-5 has upper and lower parts 5 and 4 which, when the mould is closed as shown in Figures 2 and 3, define between them a cavity 11. The cavity 11 has at its centre a tubular protrusion 12 into the mould part 5. This will form a gas inlet port 3 for the finished mask 20 (Figure 1). The cavity 11 has a relatively thin central region 7 which will form the shell 13 of the mask and a relatively thicker outer region 9 into which material for the cushion 15 will be injected.

The mould part 4 has a tubular slot 16 in which a tubular metal barrier member 6 is movable. In the closed position of the barrier 6 as shown in Figure 2 it isolates the regions 7 and 9 of the

mould cavity 11. When withdrawn as shown in Figure 3 it allows communication between the two regions of the mould cavity.

The manufacturing procedure is as follows. With the barrier 6 closed a polymer such as transparent polypropylene is injected in a liquid state into the central region 7 of the mould cavity until it fills the same. The polymer in the cavity is allowed at least partially to solidify before the barrier 6 is withdrawn and a second, softer polymer such as a a thermoplastic elastomer is injected in a liquid state into the outer region 9 of the mould cavity. The molten, second polymer will immediately bond to the periphery 8 of the already moulded shell 13 of the mask (Figure 3).

The second, soft polymer injected into the cavity region 9 contains a small proportion of a foaming agent which will release a gas, typically carbon dioxide, when hot. On contact with the relatively cooler mould parts 4,5 the material injected into the outer cavity region 9 forms a skin while its core within the skin remains molten (Figure 3).

The mould is now opened (Figure 4) causing the second, soft polymer to inflate to form the cushion 15 and then the finished mask is ejected from the upper part 5 of the mould (Figure 5).

Injection moulding techniques using a foaming agent to produce differential expansion of different parts of a moulded article are known per se, e.g. from WO 97/03800, so that more detailed description is deemed unnecessary. The present invention applies such techniques to the production of an article which has a relatively hard, usually transparent, central component or shell with an annular cushion bonded to its periphery. The shell and cushion are necessarily of different materials traditionally giving rise to the production problems referred to in the preamble of this Specification.

If the inflation of the cushion 15 is deemed insufficient gas can be introduced directly into cavity region 9 during the foaming process. Alternatively gas can be introduced into the polymer melt before injection. Supplementary gas inflation of the cushion 15 may be desirable for many reasons. Less of the expensive foaming agent will be required and gases with higher molecular weights than carbon dioxide, gases less likely to permeate the cushion wall, can be used. These gases have the advantage of reducing the deflation or contraction rate of the cushion. The inflation/deflation characteristics of the cushion may be more precisely controlled.

Figures 7-11 illustrate two moulds 100 and 110. The moulds have a common upper part 120 and differing lower parts 130 and 140 which separate across the mould cavity. By comparison with the mould part 130 the mould part 140 provides the mould cavity with a peripheral enlargement 150. The mould part 130, on the other hand, has a stepped formation 160 at the periphery of the mould cavity which will give a thinned periphery 260 to the shell 170 moulded between the mould parts 120 and 130.

An optically clear polymer such as polypropylene is injected into the cavity of the closed, first mould (Figure 8). The upper mould part 120 has a blind annular bore 180 central to the mould cavity which will provide the moulded shell 170 with a port 190. The shell 170 will be sufficiently rigid to allow the port 190 to be connected to e.g. an airline without the necessity for additional connecting elements.

When the shell 170 has sufficiently solidified the mould 120,130 is opened, the shell 170 remaining with the upper mould part 120 (Figure 9). It will be observed that the shell 170 has a thinned periphery 200.

The shell 170 is now transported with the mould part 120 to the second mould part 140 and the second mould 120,140 is closed (Figure 11). The peripheral enlargement 150 of the mould part 140 causes there to be an annular cavity around the periphery of the shell 170 and into this a thermoplastic elastomer is injected to provide a cushion 210 which will bond to the shell 170 (Figure 11). This bond is enhanced by ingress of the cushion material into the rebate within the mould cavity formed by the thinned periphery 160 of the shell 170 such that the shell and cushion have overlapping tongues 260 and 216 (Figure 6). When the cushion 210 is sufficiently solidified the second mould 120,140 is opened (Figure 12) and the finished mask ejected.

Figure 12 illustrates a mask similar to that of Figure 6, all like parts having like reference numerals, except that the mask of Figure 12 is provided with an elastic head band 300 integral with the cushion 210. This head band has been manufactured simultaneously with the cushion 210 by the provision of a groove (not shown) in the second mould part 140 opening at both ends to the cavity in which the cushion 210 is formed. When the thermoplastic elastomer is injected into this cavity it also runs around the groove to form the head band 300. It will be understood

that the first or upper mould part 120 extends over the area of the second mould part 140 in which the groove is formed, when the mould is closed, so as to form with the groove a tunnel in the mould through which the elastomer runs.

By the provision of suitable grooving in the second mould part fastening means other than a continuous head band 300 can be provided, such as two straps which will be tied together behind the head to hold the mask in place.

The present invention allows the manufacture of anatomical masks to be automated and to be carried out at great speed. Conventional techniques take several minutes, whereas it is believed that masks can be manufactured by the method of the present invention at a rate of one or more (dependant on the number of cavities) every 30 seconds per tool cavity. This will permit a considerable reduction in the price of anatomical masks with the advantages aforedescribed.

CLAIMS:

1. A method of manufacturing an anatomical mask (as herein defined) which comprises forming or placing in a mould a central component of the mask comprising a first, relatively hard polymeric material and introducing into a mould a second relatively soft polymeric material to contact and bond to the periphery of the central component whereby the second polymeric material will form a cushion around the periphery of the central component.

2. A method as claimed in claim 1, wherein the first polymeric material is transparent polypropylene and the second polymeric material is a thermoplastic elastomer.

3. A method as claimed in either preceding claim, wherein the first polymeric material is allowed at least partially to solidify before exposure to the second polymeric material.

4. A method as claimed in any one of the preceding claims, wherein the central component is moulded in a first mould and is then transferred to a second mould the cavity of which has a peripheral enlargement in which the cushion is moulded in contact with the periphery of the first component.

5. A method as claimed in claim 4, wherein each of the moulds is of two parts, one part being common, said one part being transferred with the moulded first component to a second part of the second mould, the second part of the second mould differing from the second part of the first mould by said peripheral enlargement of the cavity.

6. A method as claimed in claim 4 or claim 5, wherein the cavity of the first mould is shaped to provide the first component with a thinned periphery which in the second mould is mated with a thinned periphery of the cushion.

7. A method as claimed in any one of claims 4-7, wherein the second mould is formed with at least one groove communicating with said cavity to provide fastening means for the mask.

8. A method as claimed in claim 7 as appendant to claim 5, or claim 6 as appendant to claim 5, wherein said groove is formed in the surface of the second part of the second mould which confronts the first mould part when the mould is closed.

9. A method as claimed in any one of claims 1-3, wherein said second relatively soft polymeric material contains a foaming agent and the method comprises opening the mould after the second polymeric material has formed a skin where it contacts the mould but before the second polymeric material has fully solidified whereby the second polymeric material will expand to form a cushion around the periphery of the central component.

10. A method as claimed in claim 9, wherein a removable barrier is placed within the mould to define the periphery of a central area of the mould cavity, the first polymeric material being injected into said central area in a liquid state and allowed to solidify before removal of the barrier and injection into an outer area of the the mould cavity of the second polymeric material in a liquid state.

11. A method as claimed in claim 9 or claim 10, wherein gas from a source other than the foaming agent is introduced into the cushion material before the latter has solidified.

12. A method as claimed in claim 11, wherein a gas is introduced under pressure into the second polymeric material before its introduction into the mould.

13. Apparatus when used to carry out the method of any one of claims 1-3 and 9-12, the apparatus comprising a mould having two parts separable across a cavity defined between the parts when the mould is closed, the cavity having a central, relatively thin area to form the central component of the mask and an outer relatively thicker area into which the second polymeric material will be injected, said two areas being separable by a removable barrier which, when present in the mould, defines the periphery of the central component of the mask.

14. Apparatus as claimed in claim 13, wherein the barrier is tubular and is movable into or out of the mould through a tubular slot in one of the mould parts.

15. Apparatus for use in carrying out the method of any one of claims 1-8, the apparatus comprising two moulds each having two parts separable across a cavity defined between the parts when the mould is closed, the cavity of the second mould having a peripheral enlargement in which the cushion will be moulded, one part of the two moulds being common and the other part of the second mould differing from the other part of the first mould by the peripheral enlargement of its cavity in which the cushion will be moulded.

16. Apparatus as claimed in claim 15, wherein said other part of the first mould has a step at the periphery of the cavity which will provide the first component with a thinned periphery.

17. Apparatus as claimed in claim 15 or claim 16, wherein said other part of the second mould is provided with a groove communicating with said peripheral enlargement to provide fastening means for the mask.

18. Apparatus as claimed in claim 17, wherein the groove communicates at both ends with said peripheral enlargement to provide the mask with an elastomeric head band.

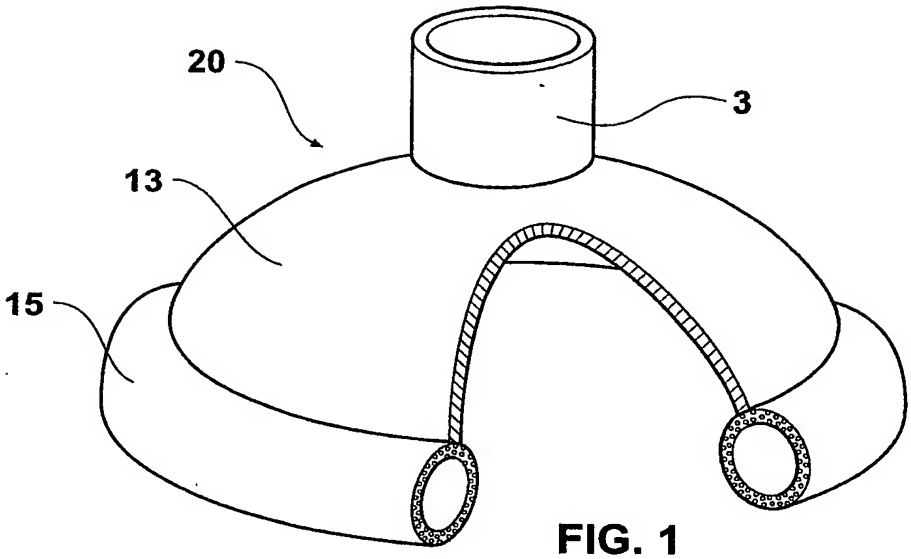

FIG. 1

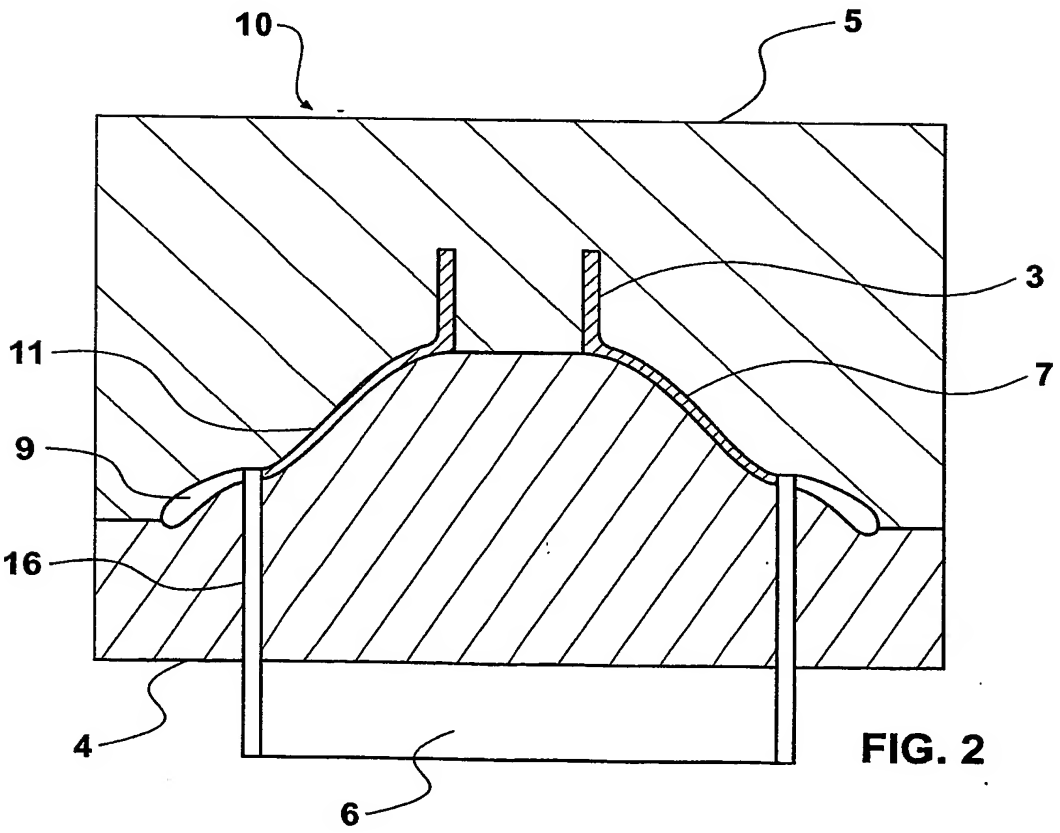

FIG. 2

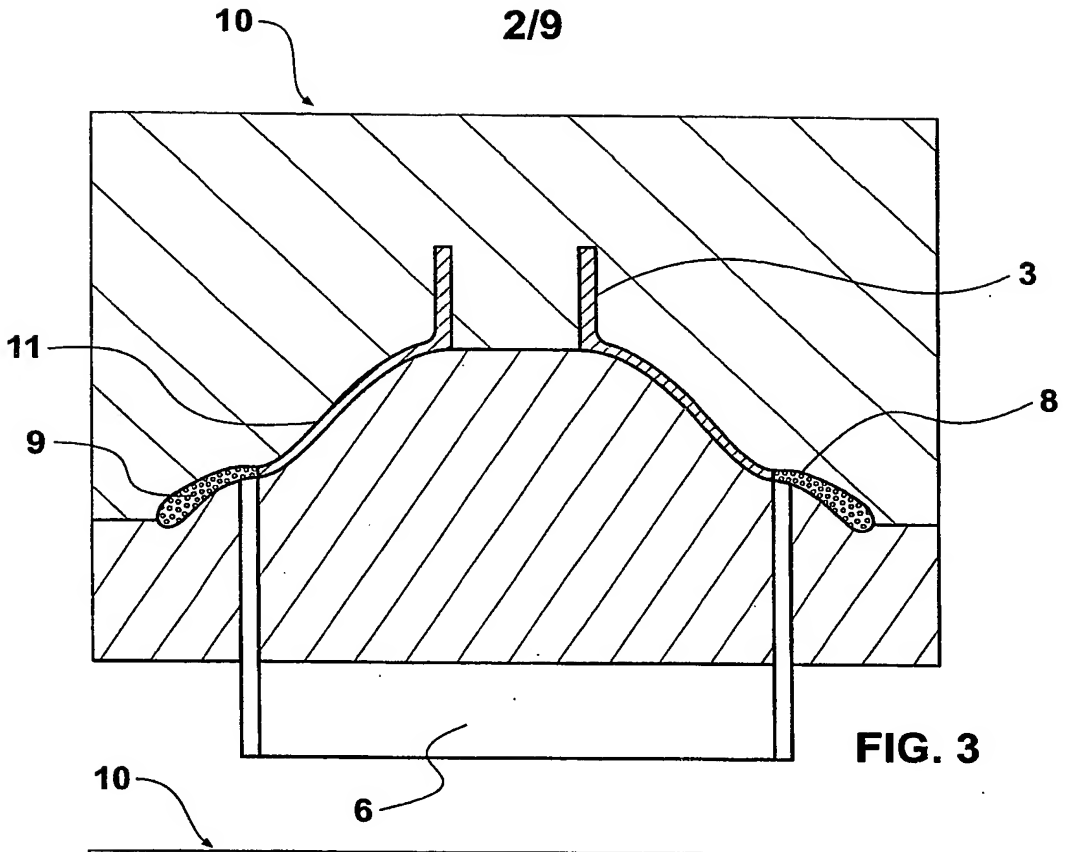

FIG. 3

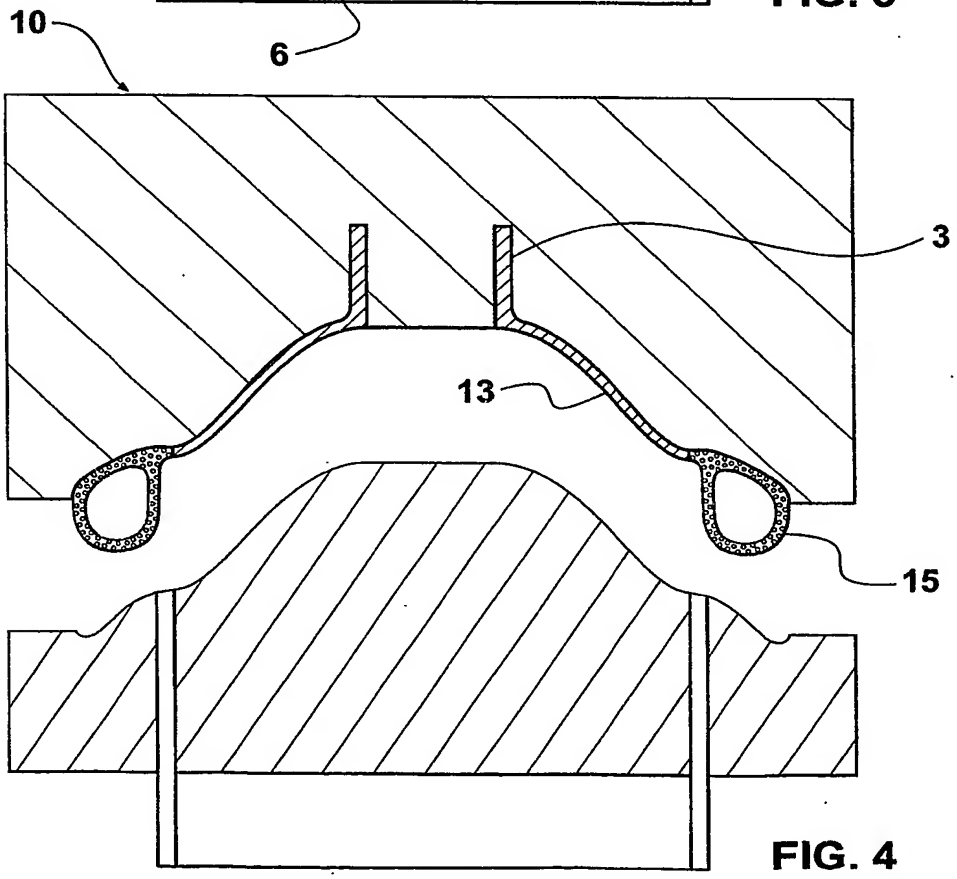

FIG. 4

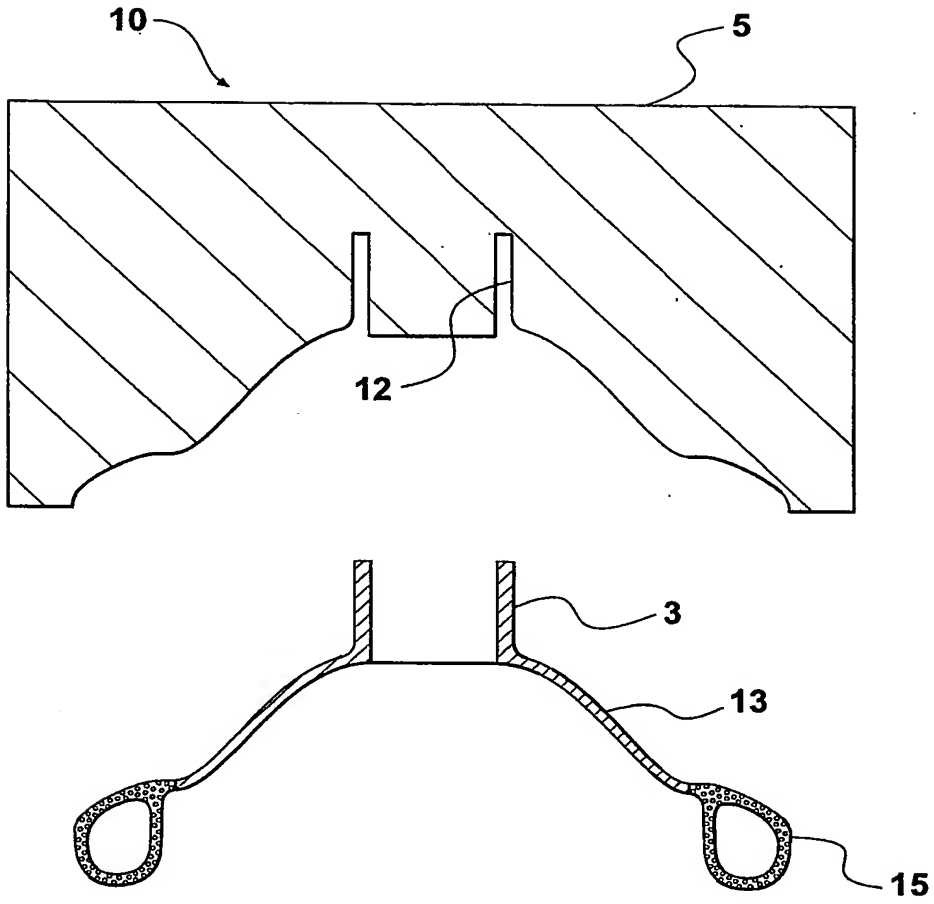

FIG. 5

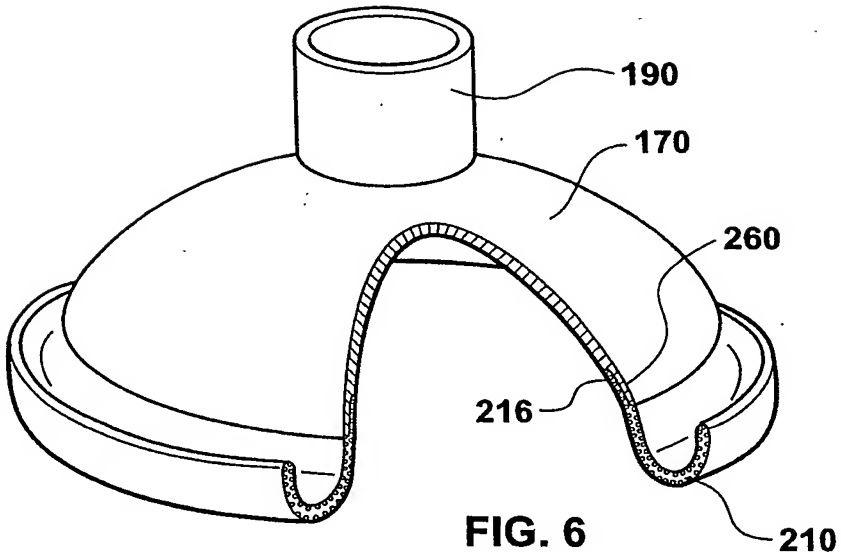

FIG. 6

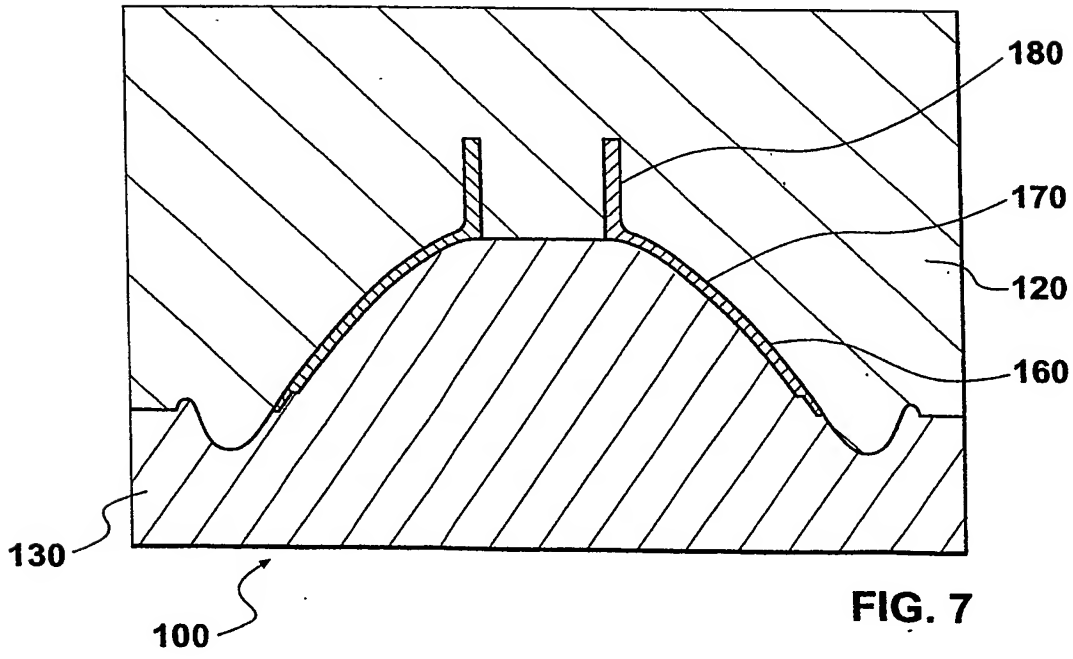

FIG. 7

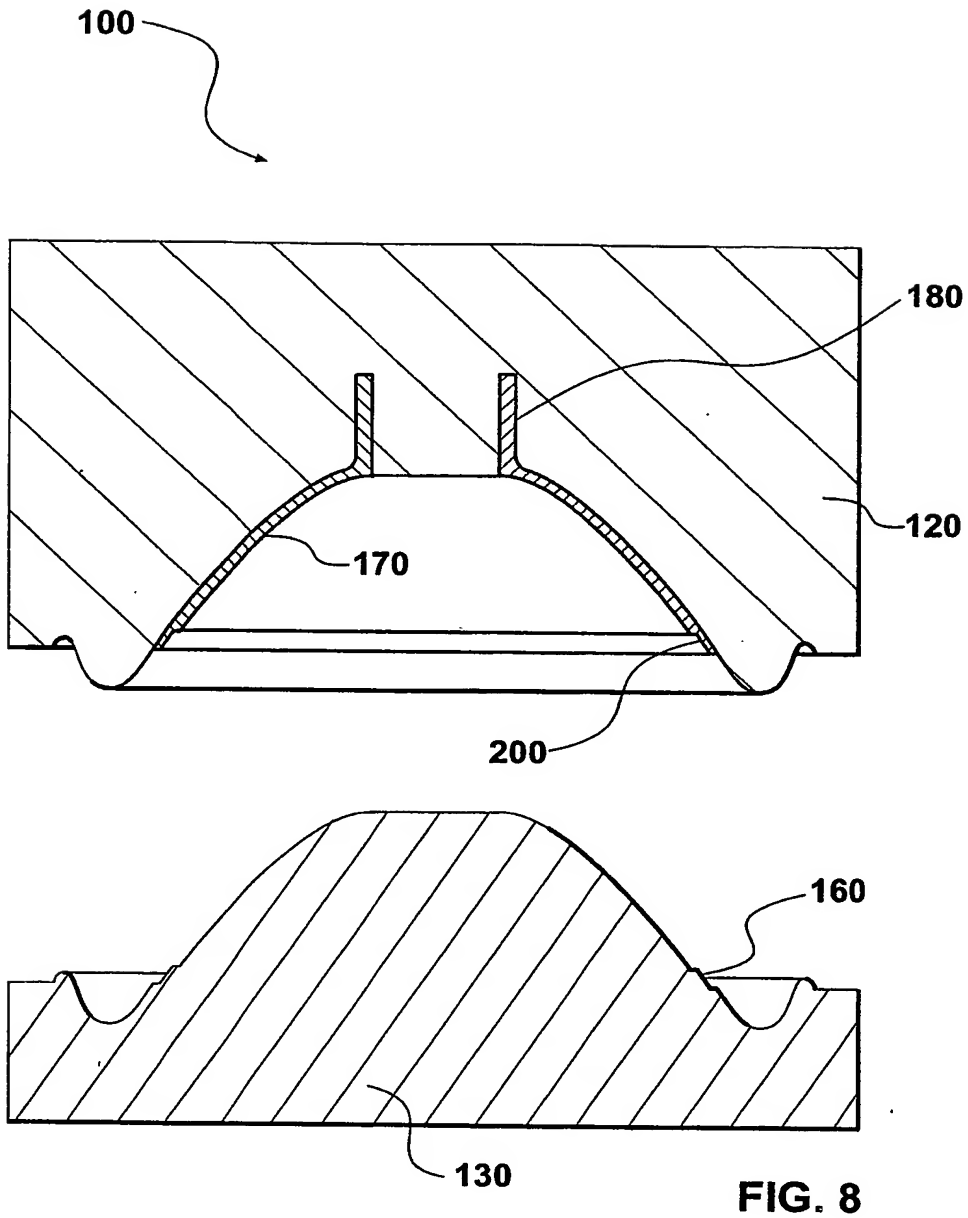

FIG. 8

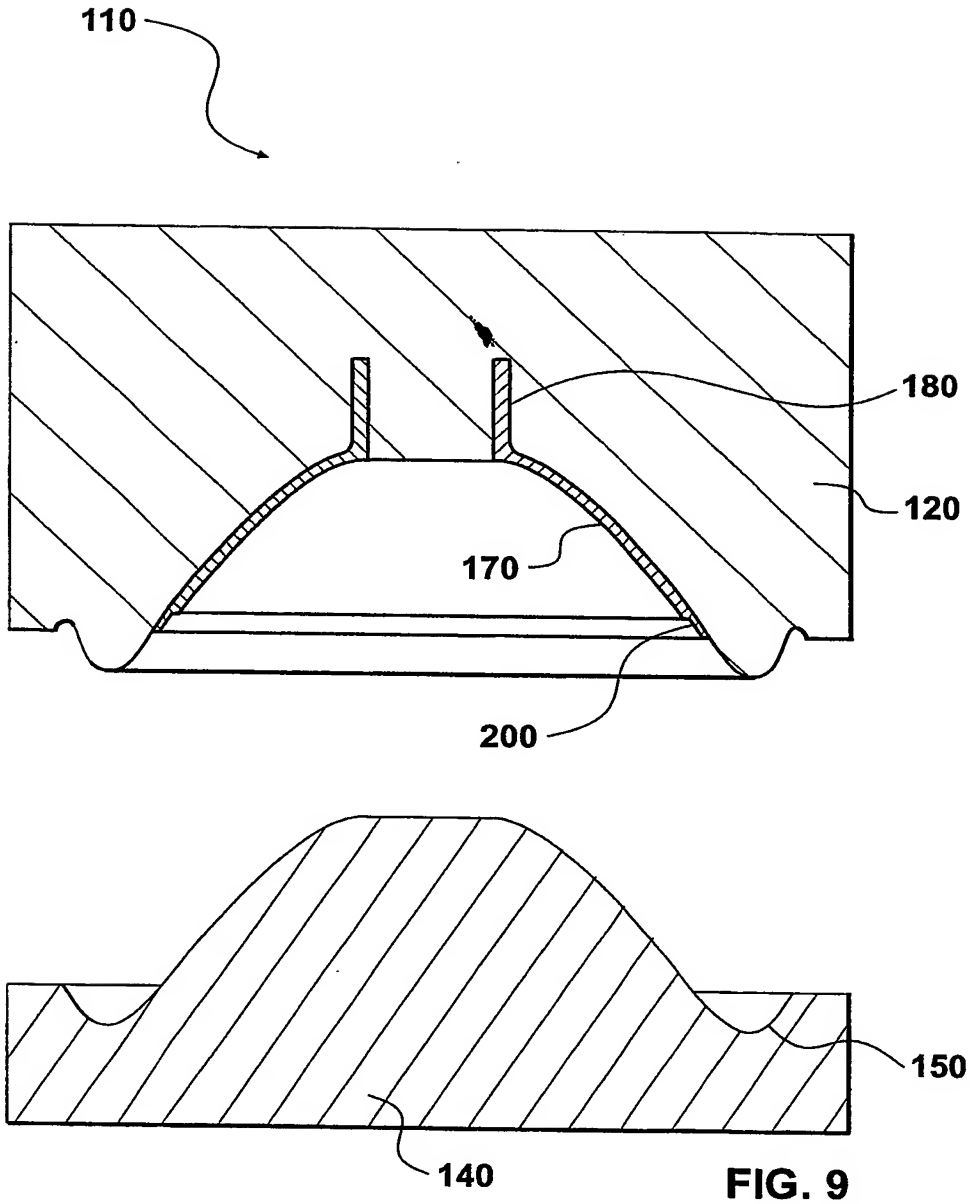

FIG. 9

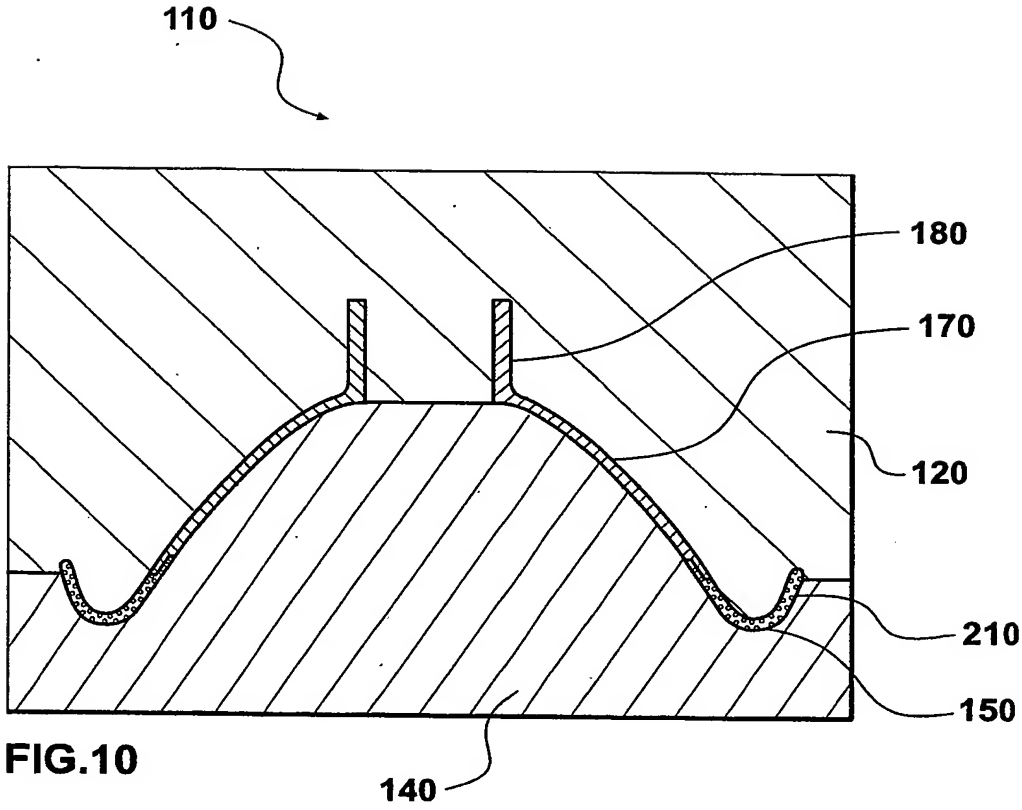

FIG.10

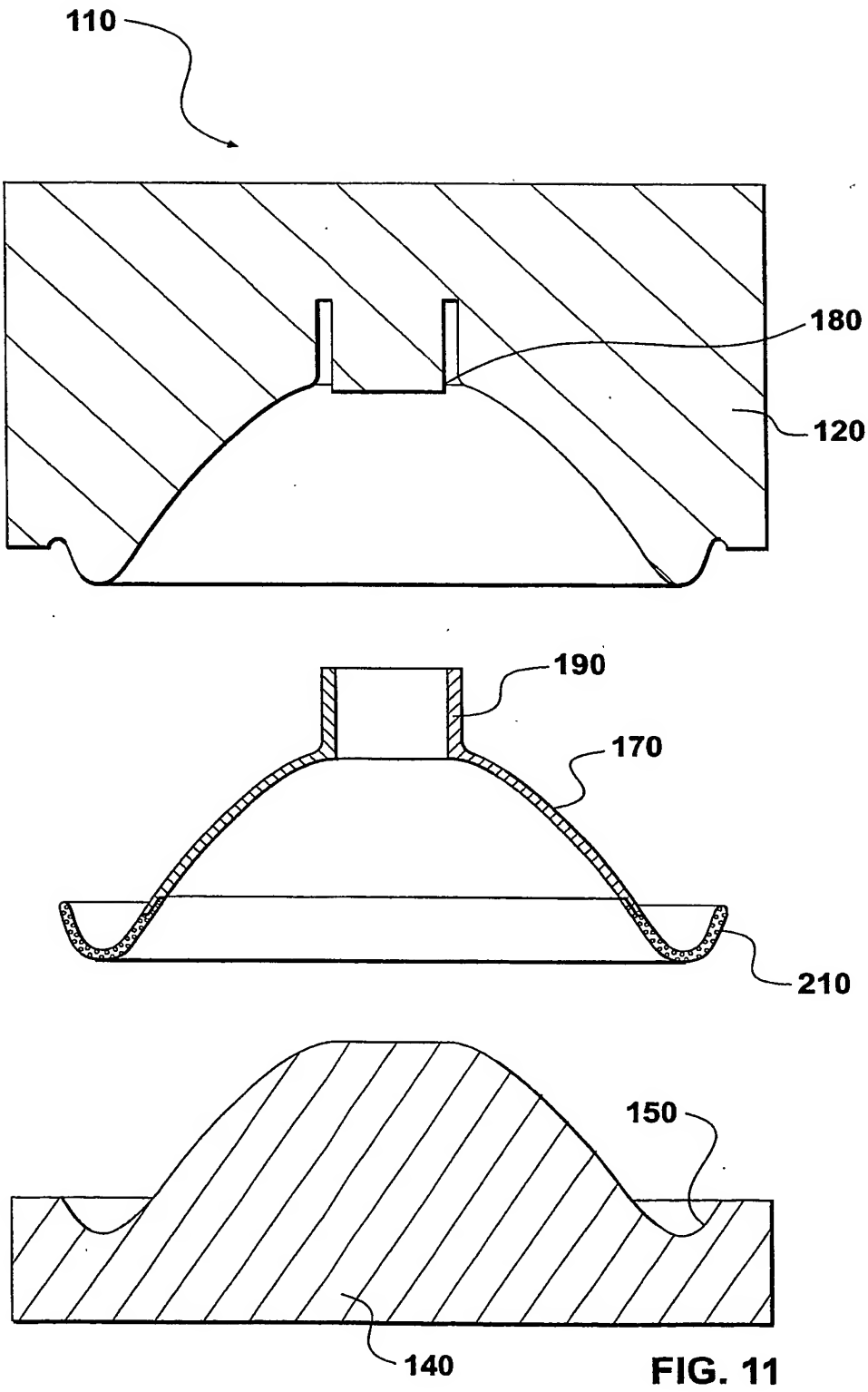

FIG. 11

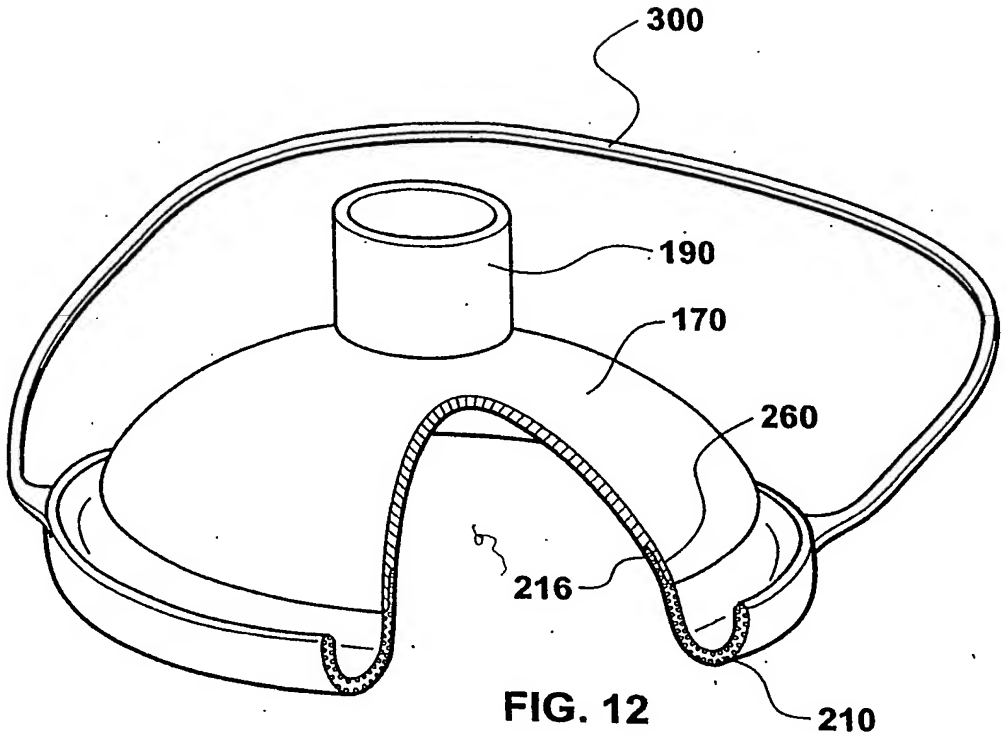

FIG. 12

INTERNATIONAL SEARCH REPORT

tional Application No
PCT/GB 02/03565

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B29C45/16 B29C45/17 A61M16/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B29C A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 3 612 783 A (SCHNEIDER KUNO) 12 October 1971 (1971-10-12) column 2, line 59 - line 65 column 3, line 31 - line 68; figure 5	10,13,14

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2002	04/12/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bollen, J

Form PCT/ISA/210 (second sheet) (July 1992)

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